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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/677,757      | 10/01/2003  | Steven F. Bierman    | VINTL.130A          | 4925             |

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EXAMINER

MEHTA, BHISMA

ART UNIT PAPER NUMBER

3767

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                      |  |
|------------------------------|-----------------|----------------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)         |  |
|                              | 10/677,757      | BIERMAN, STEVEN F. ✓ |  |
|                              | Examiner        | Art Unit             |  |
|                              | Bhisma Mehta    | 3767                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/29/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. Part of the information disclosure statement filed March 29 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The references, which have been crossed out by the examiner, have not been considered because there is no concise explanation of relevance for these references.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the medical article having at least one hole and the at least one post of the retainer being inserted through the hole must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference character 300 is mentioned in line 2 of page 10 and reference character 360 is mentioned in line 17 of page 11. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The use of the trademark Arrow MAC has been noted in the title of this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The disclosure is objected to because of the following informalities:
- a. In line 17 of page 8, there is a grammatical error in the phrase "when the are of the anchor pad".
  - b. In lines 14-15 of page 12, there is a grammatical error in the sentence beginning with "As can be seen...".
  - c. In line 29 of page 13, there is a grammatical error in the phrase "the cap 150 it off".

Appropriate correction is required.

### ***Claim Objections***

6. Claims 8-17 are objected to because of the following informalities: In line 5 of claim 8 and in line 6 of claim 17, there appears to be a grammatical error in the phrase "...and at a head...". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3-9, and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bierman (U.S. 6,213,979). In Figures 11 and 12, Bierman shows a releasable medical line securement system comprising a retainer with a base (21c), a post (25c), and a cap or cover (22c) with a recess (34c). The cap is attached to the base of the retainer by a flexible connection (24c). The post has a protrusion or head (26c). Bierman teaches that, in the covered configuration, the protrusion is within the recess and that, in the uncovered configuration, the protrusion is not within the recess. In lines 32-56 of column 10, Bierman teaches that a medical article (13) having holes (77) may be used with the retainer where the holes of the medical article are placed over the posts and then the cap is placed in a covered position. Also, the holes of the medical article are smaller than the head of the post. This serves to secure and inhibit the medical article from lateral and longitudinal motion. In Figure 3, the size of the collar (38) on the open end of the recess is smaller than a dimension of the protrusion of the post that is received in the recess and thus causes the protrusion to be held in a snap-fit

arrangement. The retainer is disposed on the upper surface of an anchor pad (16) and there is an adhesive layer on the lower surface of the anchor pad. Figure 2 shows a tab (48) on the cap (22) which is used to enable one to remove the cap from the post. In Figure 11, the base, post, and cap are shown to be integrally formed. Bierman teaches the method of releasably securing a medical article to a patient as claimed. In lines 20-30 of column 20, Bierman teaches that the various features disclosed may be interchanged between the different embodiments.

9. Claims 1-8 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bierman et al (U.S. 6,582,403). In Figures 20 and 22, Bierman et al show a releasable medical line securement system comprising a retainer with a base (222), posts (230, 250), and a cap (224) with a recess (258). The cap is attached to the base of the retainer by a flexible connection (264). Figure 9 shows the post having a protrusion or head (98). Bierman et al teach that, in the covered configuration, the protrusion is within the recess and that, in the uncovered configuration, the protrusion is not within the recess. In lines 11-34 of column 17, Bierman et al teach that a medical article having holes may be used with the retainer where the holes of the medical article are placed over the posts and then the cap is placed in a covered position. This serves to secure and inhibit the medical article from lateral and longitudinal motion. In the embodiment of Figure 3, Bierman et al show a retainer with two posts and two caps (20, 22). As to claims 3, 4, 11 and 12, in lines 1-4 of column 22, Bierman teaches that the recess (258) may one or more chamfered edges. The chamfered edges of the recess (258) are not shown. However, in Figure 30 and in lines 43-59 of column 22, Bierman

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et al teach that the chamfered edge (288) of receptacle (284) slopes inward toward the center of the receptacle to cause a snap-fit arrangement with the keeper (272).

Therefore, a chamfered edge on recess (258) would provide a collar on the open end of the recess where the opening of the collar is smaller than a dimension of the protrusion of the post that is received in the recess and thus causes the protrusion to be held in a snap-fit arrangement. The retainer is disposed on the upper surface of an anchor pad (14) and there is an adhesive layer (23 in Figure 1) on the lower surface of the anchor pad. Figure 7 shows a tab (90) on the cap (22) which is used to enable one to remove the cap from the post. In Figure 19, the base, post, and cap are shown to be integrally formed. Bierman et al teach the method of releasably securing a medical article to a patient as claimed. In lines 12-32 of column 23, Bierman et al teach that the various features disclosed may be interchanged between the different embodiments.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over Bierman et al (U.S. 6,582,403) in view of Bierman (U.S. 6,491,664). Bierman et al ('403) disclose the invention substantially as claimed. However, Bierman et al ('403) do not disclose the size of the hole of the medical article being smaller than the size of the head of the post. Bierman et al ('664) disclose a releasable medical line securement system where the medical article has holes (74) which are smaller than the heads (30) of the posts and teach, in lines 13-26 of column 9, that the smaller sized holes inhibit movement of the medical article. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the holes of the medical article of Bierman et al ('403) to make them smaller than the head of the post as taught by Bierman et al ('664) as both Bierman et al ('403) and Bierman et al ('664) teach using a securement device in the form of a retainer to anchor a medical article to a patient's body and Bierman et al ('664) specifically teaches that the smaller holes on the medical article are used to prevent movement of the medical article.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an

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invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN SIRMONS  
PRIMARY EXAMINER

